Tbilisi Balneological Spa - SPA National Scientific and Practical Health and Medical Rehabilitation, Georgia Centre

CLINICAL EFFICACY STUDY OF 'CAMELIN-M3' IN OSTEOARTHRITIS THROUGH PHYSICAL AGENTS

Introduction This clinical report is related to the new dosage form 'Kamelin-M3-ointment', produced on the basis of the standard basic drug 'Kamelin-M1-injections'. Kamelin ointment is intended for external application to the skin and mucous membranes. This modern original drug is currently registered in Georgia and the preparation of registration dossiers in many other countries is underway. Kamelin in the form of an ointment has been studied in the treatment of patients with inflammatory rheumatic diseases: osteoarthritis and osteochondrosis, the first time the drug has been administered by ultraphonophoresis.
Due to the fact that the test drug completely fulfils the requirements for the original drug, it is clear that all the data for 'Kamelin-M1' apply to the drug 'Kamelin-M3' in ointment form.

Biopharmacology of Kamelin ointment. Since the tested ointment contained the active substance in the form of 'Kamelin- M', the need to prove the bioequivalence of the test drug completely disappeared. The effect of the drug is the result of the combined effect of the bee honey components (specifically - Kamelin-M") included in the ointment, so kinetic observations are not possible. The study was an open-label, randomised, single-dose cross-distribution study at a single study site.

CLINICAL TRIAL PROTOCOL

1. Name of the clinical trial
The use of Kamelin-M3-ointment ultraphonophoresis in the clinic for the treatment of the following rheumatic inflammatory diseases: osteoarthritis (synovitis, Baker's cyst) and osteochondrosis with root syndrome.

2. Clinical trial phase:
Clinical and laboratory examination was carried out before and after treatment.

3. Names of institutions where the survey was conducted:
Tbilisi Balneological Spa- SPA National Scientific and Practical Centre for Health and Medical Rehabilitation, Georgia.

4. Study objective:
Determining the clinical outcome of Kamelin-M3-mast ultraphonophoresis in the treatment of the following rheumatic inflammatory diseases: osteoarthritis (synovitis, Baker's cyst) and osteochondrosis with root syndrome.

5. Inclusion criteria for patients in the study
Determination of inclusion criteria and treatment of patients was carried out using the above methods, and treatment was carried out after diagnosis. Patients with exacerbations of various diseases or sensitive to the components of the ointment
camellin were not included in the study group.
If any sensitisation or adverse reactions were detected, treatment was discontinued. An informed consent agreement was entered into with patients.

6. Description of the study
When the patient was admitted, he was examined by a doctor. All joints were checked (deformity, congestion, swelling). Their functional status was assessed (rotation, contracture). Once pathology was detected, laboratory tests (CRP and ESR) and instrumental tests (radiography of the affected joint and panoramic echoscopy) were carried out.

Forty patients aged 25-79 years were studied. With the following rheumatic diseases: osteoarthritis (including complicated forms: reactive synovitis, Baker's cyst,
bursitis, tendonitis) and osteochondrosis of the spine (including with root syndrome).

Patients mainly complained of the following symptoms: joint pain and swelling, restricted joint mobility, morning stiffness. With osteochondrosis - pain in some parts of the spine, sometimes a positive Lasegue sign. All patients objectively: radiographically - joint fissure narrowing, osteophytes; intervertebral space narrowing, hook-like growths. Panoramic echoscopy - uneven articular cartilage and reduction in size, osteophytes, varying amounts of inflammatory fluid. In blood - elevated ESR and CRP.
For all patients included in the study, the physiotherapeutic Kamelin-M3-mast ultraphonophoresis procedure was carried out as a primary treatment, on the affected joints and affected spinal segments, according to the classical method. The duration of the treatment was 15 days.

After the course of treatment, patients were re-examined with the results recorded.

7. Method of drug introduction: Ultraphonophoresis - Kamelin-M3-ointment
The procedure involved ultrasound irradiation of the affected joints at an intensity of 0.6-0.8 W/cm^2 , with osteochondrosis - paravertebral 0.2-0.4 W/cm^2 , continuously for 15 minutes, daily, course - 15 procedures.

8. **Description of laboratory and diagnostic procedures:** Qualitative and semi-quantitative determination of CRP was carried out by agglutination of Latex H11MATEX-CKP in undiluted blood serum (latex reagent in finished form at 2-8°C; serum is stable for 48 hours at 2-8°C).
1. The negative control should give a suspension without agglutination < 6 UI / ml CRP after 2 hours.
2. Direct agglutination indicates that the undiluted sample contains 6 UI/ml CRP.
3. Positive serum should be checked carefully in a dilution test. (Samples should be diluted with glycine-NaOH buffer). The last dilution that gives a clear agglutination is multiplied by 6 and the result in UI / ml CRP is obtained (Norm < 6).

CONCLUSIONS.

The patients' condition improved as a result of treatment, as expressed in both positive dynamics of subjective complaints and objective indices: significant reduction in ESR and CRP indices ($p < 0.001$), with improved echoscopic data (reduction or disappearance of synovium).
A high therapeutic effect was achieved in 35% of cases, good in 50% of patients and satisfactory in 15%. No complications or side effects were identified. A faster (in time) clinical effect was reported.
The results obtained allow us to recommend the ultraphonophoresis form of Kamelin (M3) ointment for widespread use in the clinical practice of traumatology, orthopaedics and neurology.

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